Reconsideration of the above-identified application is respectfully requested in view of the following remarks.

REMARKS

Status of the Claims

Claims 1-16 and 30-32 are pending. Claims 1-16 and 30-32 have been rejected.

Rejections under 35 U.S.C. § 112, paragraph 1

The Examiner has rejected claims 1-16 and 30-32 under 35 U.S.C. §112, first paragraph for failure to comply with the enablement requirement.

According to the Examiner, "[t]he claim(s) contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." See Office Action at page 2, second to last paragraph. More specifically, the Examiner contends "it is unclear... as to how application of the instant composition can 'prevent' scarring." See Office Action at page 3, last paragraph. The Examiner concludes, "one skilled in the art could not practice the invention without undue experimentation." See Office Action at page 3, first paragraph. Applicant respectfully disagrees with the Examiner's conclusion.

According to the M.P.E.P., "the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention." See M.P.E.P. § 2164, Eighth Edition, Rev. 5, Aug. 2006 at page 2100-186. Applicant respectfully asserts that the specification is sufficient to teach one of skill in the art would to make and use the claimed invention. Importantly, Applicant's

disclosure states, "a composition is provided to treat wounds or hypertrophic scars so as to **prevent** scar formation or reduce the size of the scars and improve the appearance thereof." See Applicant's Specification at page 16, line 24 through page 17, line 1 (emphasis added). This section of Applicant's disclosure goes on to disclose useful compositions for preventing scar formation, stating "[i]n this form of the invention, an active ingredient in the form of a steroid is added to the film-forming carrier." See Applicant's specification at page 17, lines 1-19. The specification continues, the composition "can be readily and directly applied to the affected tissue. The composition forms a solid, tangible film as above described which maintains the steroid active ingredient juxtaposed to the wound or scar tissue and provides an advantageous and continuous healing effect of the steroid." See Applicant's Specification at page 17, lines 10-14. Nevertheless, the Examiner states, "[t]he working examples are insufficient to establish the method of treating healed wounds to 'prevent' scarring." See Office Action at page 4, first paragraph. However, Applicant notes that, "[c]ompliance with the enablement requirement... does not turn on whether an example is disclosed." See M.P.E.P. §2164.02, Eighth Edition, Rev. 5, Aug. 2006 at page 2100-189. Again, Applicant respectfully asserts that in light of the specification one of skill in the art would know how to make and use the claimed invention.

Reconsideration and withdrawal of this rejection is respectfully requested.

Double Patenting Rejection

The Examiner has provisionally rejected claims 1, 5-16, 30 and 31 as claiming the same invention as that of claims 1-17 of copending Application No. 10/715,183. See Office Action at page 5, second paragraph.

It is Applicant's intention to allow the '183 Application to go abandoned. As such, this rejection is rendered moot. Removal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 1-8, 10-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Zhang (U.S. Pat. No. 6,528,086). Applicant respectfully traverses this rejection.

According to the Examiner, Zhang discloses "methods and formulations for dermal drug delivery on a human body surface comprising less than solid anesthetic formulations and delivery systems that can be applied to the skin or compromised surfaces and subsequently converted to a soft coherent solid state and then peeled off after the anesthetic effect is achieved. (see Abstract); (column 1, lines 9-23). The formulation comprises a topically delivered drug, a conversion agent and a vehicle medium or carrier, wherein the drug is dispersed in the carrier (col. 3, lines 20-22)." See Office Action at page 6, second paragraph. The Examiner then concludes, "given the explicit teachings of Zhang delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made." See Office Action at page 8, last paragraph.

Applicant respectfully asserts that Zhang does not teach or suggest the method presently claimed. Claim 1 of the present invention is directed to, "[a] method of treating healed wounds so as to prevent, or reduce scarring and/or improve the appearance of scars comprises; applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible member juxtaposed to the healed wound thereby reducing scarring or

improving the appearance thereof." See claim 1 (emphasis added). As such, it is clear that the method presently claimed is directed to the reduction of scarring and requires applying the composition claimed onto a healed wound. This method is not taught or suggested by Zhang et al. Zhang et al. is broadly directed to a method and device for dermal drug delivery. According to Zhang et al. the composition of Zhang et al. is "applied to certain human body surfaces," Zhang continues, "such as skin having an abrasion, laceration, or post-surgery wound." See Zhang et al. at col. 1, lines 9-18. Zhang et al. does not disclose the application of the composition of Zhang et al. to healed wounds. As the Examiner points out, Zhang et al. goes on to list numerous drugs which can be delivered by the method and composition of Zhang et al. See Office Action at page 7, second to last paragraph; see also Zhang et al. at col. 11, line 16 through col. 14, line 64. However, importantly Zhang et al. does not disclose any drugs for the treatment of, or reduction in appearance of scar tissue. In fact, Zhang et al. makes no mention of treating or reducing scar tissue whatsoever. As such, it is clear that Zhang et al. does not disclose or suggest the use of the composition to treat a healed wound and does not disclose or suggest reducing the appearance of scar tissue. Therefore, Applicant respectfully asserts that Zhang et al. does not teach or suggest all the claim limitations of claim 1, and thus, claim 1 is not and cannot be rendered obvious by Zhang et al. Claims 2-16, which depend directly or indirectly from claim 1 are also not rendered obvious by Zhang et al.

Claim 30, like claim 1, is directed to a method to "prevent or reduce scarring and/or improving the appearance of scars" by "applying onto a healed wound" a composition therefore. See claim 30 (emphasis added). As pointed out above, Zhang et al. does not disclose or suggest treating a healed wound or reducing the appearance

of scar tissue. As such, Applicant respectfully asserts that claim 30, and claim 31 which depends therefrom, are not and cannot be rendered obvious by Zhang et al.

Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner has rejected claim 9 under 35 U.S.C. §103(a) as being unpatentable over Zhang (U.S. Pat. No. 6,528,086) in view of Tipton et al. (U.S. Pat. No. 5,632,727). Applicant respectfully traverses this rejection.

According to the Examiner, "Zhang teaches vitamins, such as vitamins A & D (see column 11, lines 32-33). [However,] Zhang does not teach Vitamin E." See Office Action at page 9, third paragraph. Furthermore, the Examiner states, "Tipton et al. ('727) teach a biodegradable film dressing and methods of using the film dressing to treat injured tissues and deliver biologically active agents within the film comprises vitamins, such as vitamin E (see reference column 10, lines 17-21)." See Office Action at page 9, fourth paragraph. According to the Examiner, "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the vitamin E as taught by Tipton et al. within the delivery formulations of Zhang." See Office Action at page 9, fifth paragraph.

As Applicant has pointed out hereinabove, Zhang et al. does not disclose or suggest the application of the composition to a healed wound and does not disclose or suggest reducing the appearance of scar tissue. Tipton et al. does not make up for these deficiency. The biodegradable film of Tipton et al. "can be used to provide protection and promote healing of injured tissue and/or for delivery of biologically active agents or substances." See Tipton et al. at col. 2, lines 20-23 (emphasis added). Furthermore, according to Tipton et al., "the biological agent can act to enhance cell growth and tissue regeneration, cause nerve stimulation or bone growth, prevent

infections, promote wound healing and/or provide pain relief." See Tipton et al. at col. 3, lines 25-30. Tipton et al. does not teach or suggest the application to a healed wound for reducing the appearance of scar tissue. As such, Applicant respectfully asserts that the combination of Zhang et al. and Tipton et al. does not teach all the claim limitations of the presently claimed invention, and thus, does not and cannot render the present claims obvious.

Reconsideration and withdrawal of this rejection are respectfully requested.

Respectfully submitted,

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Date

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